510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Acueity, Inc.
100 Hamilton Avenue, Suite 140
Palo Alto, CA 94301

Telephone: (650) 473-9910
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B. Contact Person

Nancy Lincé
Regulatory Affairs Consultant

Telephone: (650) 759-6186

C. Date Prepared

August 12, 2003

D. Device Name

Trade Name: Excisor Bioptome
Classification Name: Instrument, Biopsy

E. Device Description

The Excisor Bioptome is a percutaneous, mechanical coring device utilizing imaging guidance such as ultrasound and X-ray for breast biopsy. The basic structure of the device includes a Motorized Cutter and detachable stainless steel Introducer with aluminum handle or finger piece and aspiration port and a stainless steel trocar.

F. Intended Use

The Acueity Excisor Bioptome is a multiple action biopsy system intended for obtaining a soft tissue breast biopsy. The instruments are to be used for diagnostic purposes only and are not intended for therapeutic use.

G. Substantial Equivalence

The Excisor Bioptome is substantially equivalent to the US Biopsy Single Action Bioipsy Device (K954231) and the Ethicon Mammotome Hand Held System (K991980). It has the same intended use, materials and principles of operation as the predicate devices. All three devices are designed to perform percutaneous breast biopsy using a tubular cannula with trocar/needle to penetrate the tissue and access the biopsy site.

H. Device Testing Results and Conclusion

All necessary testing will be performed on the Exisor Bioptome to ensure that the product is substantially equivalent to the predicate devices and to ensure that the new device does not have a significant effect on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2003

Acueity, Inc.
c/o Mr. Peter N. Ruys
N.V. KEMA
P.O. 9035
6800 Et Arnhem
Arnhem, Netherlands

Re: K032847
Trade/Device Name: Excisor Bioptome
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: September 11, 2003
Received: September 12, 2003

Dear Mr. Ruys:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 032847

Device Name: Excisor Bioptome

Indications For Use:

The Acueity Excisor Bioptome is a multiple action biopsy system intended for obtaining a soft tissue breast biopsy. The instruments are to be used for diagnostic purposes only and are not intended for therapeutic use.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032847

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use_____

(Optional Format 1-2-96)